

the proximal end, and is configured to deliver the implant within a tissue of a patient via an incision in the skin of the patient at an implantation site.

[0005] The system also includes a placement guide comprising a first surface having a contact face and an opposite non-contact face, the first surface contact face configured to be disposed in contact with a surface of the skin of the patient at the implantation site and a pilot-tube member. The pilot-tube member projecting from the contact face of the first surface and configured to be disposed in contact with the surface of the skin of the patient at the implantation site, the pilot-tube member defining a tube therethrough, the tube comprising a proximal end configured to receive the distal end of the placement cannula, a distal end spaced apart from the proximal end of the tube at a first distance, and a longitudinal central axis arranged relative to the first surface at either or both of a second distance and an angle, wherein the placement guide is configured to guide the placement cannula within the tissue of the patient at the implantation site to effect implantation of the implant at a predetermined placement depth beneath an outer surface of the skin of the patient at the implantation site beneath the first surface contact face such that both ends of the implant are placed at equal depths, and wherein the placement cannula is movable relative to the placement guide, and wherein the placement cannula is moveable either within or adjacent to the pilot-tube member. During insertion of the cannula into the incision, prior to release of the implant from the cannula, the handle portion and cannula can be rotated by a practitioner, in clockwise and counterclockwise directions, *e.g.*, back and forth within a span or range of between about 9 o'clock to about 3 o'clock, about 10 o'clock and about 2 o'clock, or about 11 o'clock to about 1 o'clock, relative to the central longitudinal axis of the pilot-tube on the placement guide. Rotation in this manner, while the placement guide remains substantially stationary, without rotating, on the outer surface of the skin of the patient, may promote controlled and proper progression of the cannula into the tissue of the patient beneath the outer surface of skin. Thus, in some embodiments, the placement guide is configured to allow substantially free rotation of the cannula within the pilot-tube of the placement guide. In some embodiments, a system is provided for placing an implant into and/or among intraepidermal, subepidermal, intradermal, subdermal, intracutaneous, and/or subcutaneous tissue.

[0006] In such systems (and other embodiments), one and/or another of the following features may be included:

- at least one of the first distance, the second distance and the angle are configured to guide the placement cannula and deliver the implant at the determined depth beneath the outer surface of the skin of the patient;
- the placement guide further comprises a visualization window or opening which extends along a length and a width of the placement guide and which is configured to enable visualization and/or palpitation of an area of skin around the site at which the implant is being inserted;

pressure to the incision, applying an adhesive to at least one side of the incision, and closing the incision; and

- the determined depth is about 0.5 mm to about 4.5 mm, about 1 mm to about 4 mm, about 1.5 mm to about 3 mm, beneath the outer surface of the skin of the patient.

[0009] In some embodiments for placing an implant, both ends of the implant are placed at a determined depth that is substantially the same, resulting in a substantially level placement of the implant. In other words, each end of the implant is placed at a determined depth that is within about 0.5 mm, about 0.4 mm, about 0.3 mm, about 0.2 mm, or about 0.1 mm of the other end.

[0010] According to a second aspect, a placement guide for use with a placement tool is provided and includes a first surface having a contact face and an opposite non-contact face, the first surface contact face configured to be disposed in contact with a surface of the skin of a patient at the implantation site and a pilot-tube member. The pilot tube member projecting from the contact face of the first surface and configured to be disposed in contact with the surface of the skin of the patient at the implantation site, the pilot-tube member defining a tube therethrough, the tube includes a proximal end configured to receive a distal end of a placement cannula of the placement tool for delivering an implant into tissue, a distal end spaced apart from the proximal end of the tube at a first distance, and a longitudinal axis therethrough from the proximal end to the distal end. The longitudinal axis is arranged relative to the first surface at either or both of a second distance and an angle, wherein at least one of the second distance or the angle of the placement guide are configured to guide the placement cannula of the placement tool within the tissue of the patient at the implantation site to effect implantation of the implant beneath an outer surface of the skin of the patient at the implantation site beneath the first surface contact face such that both ends of the implant are placed at equal depths, and wherein the pilot tube member is configured to permit rotation of the placement cannula within the pilot tube. In some embodiments, the placement guide is made from a material (*e.g.*, medical-grade plastic) that is translucent or substantially clear. In some embodiments, the placement guide is substantially rigid. For example, in some embodiments, the placement guide is sufficiently rigid that it cannot be substantially flexed, warped or bent, length-wise and/or width-wise, by a user during normal usage. In some embodiments, a placement guide device is provided for use with a

placement tool. In some embodiments, a placement guide device is provided for placing an implant into and/or among intraepidermal, subepidermal, intradermal, subdermal, intracutaneous, and/or subcutaneous tissue.

[0011] The placement guide, according to some embodiments, may include one and/or another of the following features:

- a visualization window or opening which extends along a length and a width of the first surface and configured to enable visualization and/or palpitation of an area of skin around the site at which the implant is being inserted;

Claims:

1. A system for placing an implant, comprising:

a placement tool comprising

a handle portion, and

a placement cannula having a length, a proximal end arranged near the handle portion and a distal end opposite the proximal end, the placement cannula configured to deliver the implant within a tissue of a patient via an incision in the skin of a patient at an implantation site; and

a placement guide comprising

a first surface having a contact face and an opposite non-contact face, the first surface contact face configured to be disposed in contact with a surface of the skin of the patient at the implantation site and

a pilot-tube member projecting from the contact face of the first surface and configured to be disposed in contact with the surface of the skin of the patient at the implantation site, the pilot-tube member defining a tube therethrough, the tube comprising a proximal end configured to receive the distal end of the placement cannula, a distal end spaced apart from the proximal end of the tube at a first distance, and a longitudinal central axis arranged relative to the first surface at either or both of a second distance and an angle;

wherein the placement guide is configured to guide the placement cannula within the tissue of the patient at the implantation site to effect implantation of the implant at a predetermined placement depth beneath an outer surface of the skin of the patient at the implantation site beneath the first surface contact face such that both ends of the implant are placed at equal depths, and

wherein the placement cannula is movable relative to the placement guide, and wherein the placement cannula is moveable either within or adjacent to the pilot-tube member.

2. The system of claim 1, wherein at least one of the first distance, the second distance, and the angle of the longitudinal central axis of the tube relative to the first surface of the placement guide are configured to orient the longitudinal axis in order to guide the placement cannula for the delivery of the implant at the predetermined placement depth.
3. The system of claim 1, wherein the predetermined placement depth is 0.5 mm to 4.5 mm beneath the outer surface of the skin of the patient.
4. The system of claim 1, wherein the placement guide further comprises a visualization window or opening, wherein the visualization window or opening extends along a length and a width of the placement guide and is configured to allow visual observation and/or palpation or touch of an area of an outer surface of skin around the implantation site.
5. The system of claim 1, wherein the placement guide further comprises a visualization opening, wherein the visualization opening extends along a length and a width of the placement guide and is configured to allow visual observation and palpation or touch of an area of an outer surface of skin around the implantation site.
6. The system of claim 1, wherein the implant is an osmotic mini-pump.
7. The system of claim 1, configured to permit clockwise and counterclockwise rotation of the placement cannula within the tube and relative to the longitudinal central axis of the tube.
8. A placement guide for use with a placement tool, the placement guide comprising:

a first surface having a contact face and an opposite non-contact face, the first surface contact face configured to be disposed in contact with a surface of the skin of a patient at the implantation site; and

a pilot-tube member projecting from the contact face of the first surface and configured to be disposed in contact with the surface of the skin of the patient at the implantation site, the pilot-tube member defining a tube therethrough, the tube comprising

a proximal end configured to receive a distal end of a placement cannula of the placement tool for delivering an implant to tissue, a distal end spaced apart from the proximal end of the tube at a first distance, and a longitudinal axis therethrough from the proximal end to the distal end,

wherein the longitudinal axis is arranged relative to the first surface at either or both of a second distance and an angle,

wherein at least one of the second distance or the angle of the placement guide is configured to guide the placement cannula of the placement tool within the tissue of the patient at the implantation site to effect implantation of the implant beneath an outer surface of the skin of the patient at the implantation site beneath the first surface contact face such that both ends of the implant are placed at equal depths, and

wherein the pilot tube member is configured to permit rotation of the placement cannula within the pilot tube.

9. The placement guide of claim 8, further comprising a visualization window or opening that extends along a length and a width of the first surface and configured to enable visual observation and/or palpation or touch of an area of the outer surface of skin around the implantation site.
10. The placement guide of claim 9, wherein the visualization window or opening has a length that extends beyond a tip of the cannula when the cannula is inserted into, and fully extended through, the tube.

11. The placement guide of claim 8, wherein the predetermined placement depth is from 0.5 mm to 4.5 mm beneath the outer surface of the skin of the patient.
12. The placement guide of claim 8, wherein the pilot-tube member is configured to receive and guide the placement cannula into tissue.
13. The placement guide of claim 8, wherein the placement guide is made from a material that is translucent or substantially clear.
14. The placement guide of claim 8, wherein the tube is configured at an incline relative to the first surface.
15. The placement guide of claim 8, wherein the placement guide cannot readily be flexed or bent, length-wise or width-wise, by a user.
16. The system of claim 1, wherein the placement cannula is movable within and relative to the handle portion.
17. The placement guide of claim 8, configured to permit clockwise and counterclockwise rotation of the placement cannula within the tube and relative to the longitudinal central axis of the tube.